UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,243	11/12/2003	Solomon S. Steiner	PDT 103 CON(3)	6406

23579 7590 01/25/2007

PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE, SUITE 1200
1201 PEACHTREE STREET
ATLANTA, GA 30361

EXAMINER	
GEORGE, KONATA M	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,243	STEINER ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-26* is/are allowed.

6)☒ Claim(s) *16,17,22,27,31,32 and 36* is/are rejected.

7)☒ Claim(s) *18-21,28-30 and 33-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 16-36 are pending in this application.

Action Summary

1. The rejection of claims 16-18 and 22 under 35 U.S.C. 112, first paragraph as failing to comply with written description is hereby withdrawn.

2. The rejection of claims 23-36 under 35 U.S.C. 112, second paragraph as omitting essential steps is hereby withdrawn.

3. The rejection of claims 26 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn.

4. The rejection of claims 16 and 17 under 35 U.S.C. 103(a) over Boyes et al. is being maintained for the reasons stated in the office action dated September 29, 2005.

5. The rejection of claims 16, 19 and 20 under 35 U.S.C. 103(a) over Debenedetti et al. is hereby withdrawn.

6. The rejection of claims 16 and 21 under 35 U.S.C. 103(a) over Sugaya et al. is hereby withdrawn.

7. The rejection of claim 22 under 35 U.S.C. 103(a) over Boyes et al. in view of Hunt et al. is being maintained for the reasons stated in the office action dated September 29, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 16, 17, 27, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyes et al. (EP 0 257 915 A1).

Boyes et al. discloses a pharmaceutical formulation comprising a microcapsule having a polymeric wall material encapsulating a drug and a lipid-soluble surfactant mixed with the microcapsule or is incorporated within or coats the wall material of the microcapsule (abstract). Page 2, lines 54-55 teach that the particles range from 0.1 to 10 microns. Page 3, lines 9-14 teach the drugs which can be used in the microparticles. Page 3, lines 25-32 teach the polymeric material. With respect to the pH of the material, it is the position of the examiner that since the prior art teaches the same material as claimed, then the material would have the same inherent properties of releasing the drug at the claimed pH. The prior art does not teach the exact particle size range.

It would have been obvious to one of ordinary skill in the art to realize that since the ranges of the instant invention overlap that the prior art ranges then the ranges are obvious to one of ordinary skill. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re*

Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Response to Arguments

9. Applicant's arguments filed August 6, 2006 have been fully considered but they are not persuasive.

Applicants argue that the microcapsules described in Boyes require two components polymeric wall forming material and surfactant, whereas, the instant invention comprises only one. It is the position of the examiner that the material of the instant invention is not limited to only what is claimed. The claim language is open and other things can be contained therein. Furthermore, on page 3, lines 25-32, teach that the polymeric material can be polymers of amino acids.

Applicants also argue that the prior art does not teach the material releasing the drug at a pH of 6 or greater. It is the position of examiner that it would have been obvious to one of ordinary skill in the art to formulate the material or use a material that would release the drug at the target site having the target pH, in this case greater than 6.0.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyes et al. (EP 0 257 915 A1) as applied to claims 16 and 17 above, in view Hunt et al. (US 4,866,051).

Claim 22 is directed to a device for delivering the microparticle composition.

Boyes et al. discloses all that is recited in claim 22, except a cartridge for insertion into an inhaler. The prior art does not teach the exact particle size range.

Column 3, lines 23-27 of Hunt et al. teaches the use of inhalation cartridges comprising particles having a size below 10 microns.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teachings of Boyes et al. comprising dry particles in the invention of Hunt et al. comprising inhalation cartridges for particles. The expected result would be facilitating delivering the microparticle via inhalation.

It would have been obvious to one of ordinary skill in the art to realize that since the ranges of the instant invention overlap that the prior art ranges then the ranges are obvious to one of ordinary skill. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Response to Arguments

11. Applicant's arguments filed August 6, 2006 have been fully considered but they are not persuasive.

Applicant argues that Hunt does not teach the invention as claimed. Hunt is being relied upon to teach the use of inhalation cartridges comprising particles having a size below 10 microns. One of ordinary skill in the art could use look to the teachings of

Hunt et al. for a delivery device (inhalation cartridges for inhalers) for particles have a particle size of less than 10 microns.

Conclusion

12. Claims 16, 17, 22, 27, 31, 32 and 36 are rejected.

13. Claims 18-21, 28-30 and 33-35 are objected too. The prior art does not teach the dry particles comprising a lipid, hydrophilic or hydrophobic proteins and wherein the microparticle material is a diketopiperazine.

14. Claims 23-26 are allowed. The prior art does not teach a microparticle comprising a diketopiperazine and an active agent.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Technology Center 1600

Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600